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UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

QUALYST TRANSPORTER
SOLUTIONS, LLC,

Plaintiff,

v.

HμREL CORPORATION,

Defendant.

Civil Action No.

**COMPLAINT AND
JURY DEMAND**

Plaintiff Qualyst Transporter Solutions, LLC (“Qualyst”) brings this action against Defendant HμREL Corporation (“HμREL”) to obtain permanent injunctive relief, actual damages, attorneys’ fees, and costs for HμREL’s patent infringement.

NATURE OF THE ACTION

1. This is an action arising under the patent laws of the United States, 35 U.S.C. §§ 1 *et seq.*, including but not limited to 35 U.S.C. §§ 271 and 281, and is brought by Qualyst against HμREL for infringement of U.S. Patent No. 7,604,934 (“the ’934 Patent”) (“Patent-in-Suit”).

PARTIES

2. Plaintiff Qualyst is a North Carolina corporation located at 2810 Meridian Parkway, Durham, North Carolina 27713.

3. On information and belief, Defendant HμREL is a Delaware corporation with its principal place of business at 675 US Highway 1, North Brunswick, New Jersey 08902.

JURISDICTION AND VENUE

4. This Court has subject matter jurisdiction pursuant to 28 U.S.C. §§ 1331 and 1338(a) because this action arises under the patent laws of the United States.

5. This Court has general and specific personal jurisdiction over HμREL. HμREL has continuous and systematic contacts in New Jersey by way of its facility located in New Brunswick, New Jersey.

6. HμREL is registered to do business in New Jersey, and maintains a registered agent and a registered office in New Jersey.

7. On information and belief, venue is proper in this Court because HμREL has committed acts of infringement in this Judicial District by utilizing the patented method of screening a xenobiotic in vitro for susceptibility to in vivo biliary excretion. Venue is also proper in this Court under 28 U.S.C. §§ 1391(b) and (d) and 1400(b).

BACKGROUND

8. Qualyst was founded on breakthrough research performed at the University of North Carolina at Chapel Hill. That breakthrough technology was exclusively licensed to and made commercially available by Qualyst. Qualyst has experienced extensive growth since its founding. Qualyst counts multiple major pharmaceutical and biotechnology companies as its customers, including AstraZeneca, Johnson & Johnson, Pfizer, Gilead, Millennium, and Intermune.

9. Qualyst has become the leader in hepatic drug transporter products and contract research services utilizing its patented B-CLEAR® and B-SAFE™ technologies. The B-CLEAR® and B-SAFE™ technologies are patented methodologies that, when applied to properly functioning hepatocytes in culture, open the bile pockets (analogous to bile canaliculi in vivo), allowing the measurement of material that has been transported from inside the cell. Measurement of biliary efflux allows Qualyst to evaluate biliary clearance and biliary transporter interactions, as well as perform cellular mass balance measurements.

10. According to its website, HμREL offers the HμRELflux™ primary hepatocyte-based, direct-measurement, single-well biliary efflux assay. The launch of HμRELflux™ assay was previewed on March 18, 2015, and announced at the Science of Toxicology (“SOT”) Annual Meeting in San Diego, California on March 25, 2015.

11. On March 19, 2015, just days prior to the launch of the HμRELflux™ assay, Qualyst provided notice of the Patent-in-Suit to HμREL. Qualyst informed HμREL that it believed the HμRELflux™ assay process was covered by one or more claims of the Patent-in-Suit, among others. Qualyst suggested the parties enter into a Confidential Disclosure Agreement to discuss the HμRELflux™ assay details in order to avoid a protracted dispute.

12. Again at the SOT Annual Meeting, Qualyst informed HμREL, on March 23, 2015, and March 25, 2015, that the HμRELflux™ assay would infringe at least the Patent-in-Suit.

13. On March 27, 2015, HμREL’s outside counsel responded to the March 19, 2015 notice letter, stating that HμREL does not believe it infringes the Patent-in-Suit, among others.

14. Despite the above-referenced notices and the request for a confidential meeting, HμREL refused to meet with Qualyst and instead announced the launch of its assay at the SOT Annual Meeting and is offering the HμRELflux™ assay for sale.

15. On information and belief, the HμRELflux™ assay is performed by HμREL employees in New Jersey. Qualyst, after reasonable diligence, could not locate any public information detailing the exact steps of and procedure for the assay. However, on information and belief, alleged results of the HμRELflux™ assay can only be obtained by utilizing the method covered by the Patent-in-Suit.

16. Qualyst has requested information from HμREL describing how the HμRELflux™ assay is performed to confirm or refute HμREL's contention that it does not infringe the Patent-in-Suit. HμREL has rebuffed Qualyst's request for information, even after repeated offers by Qualyst to enter into a confidentiality agreement.

17. As a result of the dearth of information detailing the HμRELflux™ assay procedure, Qualyst consulted with an industry expert to confirm that it is more likely than not that the HμRELflux™ assay infringes one or more claims of the Patent-in-Suit.

COUNT I

INFRINGEMENT OF U.S. PATENT NO. 7,604,934

18. Qualyst incorporates Paragraphs 1 through 17 of its Complaint as if fully set forth herein.

19. On October 20, 2009, the United States Patent and Trademark Office duly and legally issued the '934 Patent, entitled "Method of Screening Candidate Compounds for

Susceptibility to Biliary Excretion by Endogenous Transport Systems," to The University of North Carolina at Chapel Hill. A copy of the '934 Patent is attached as Exhibit A.

20. Qualyst is the exclusive licensee of the '934 Patent and is the assignee of all causes of action and enforcement rights for the '934 Patent, including without limitation, the right to collect damages for past and future infringement and to seek injunctive relief.

21. The claims of the '934 Patent cover a method of screening a xenobiotic in vitro for susceptibility to in vivo biliary excretion by an endogenous sinusoidal or canalicular transport system, or by both sinusoidal and canalicular transport systems.

22. On information and belief, HμREL has infringed and is infringing, directly or indirectly, either literally or under the doctrine of equivalents, the '934 Patent by making, using, offering to sell, and/or selling within the United States, and/or importing into the United States, without authority, the methods and steps performed in the HμRELflux™ assay.

23. To the extent HμREL has not directly infringed the '934 Patent, HμREL, with knowledge of the '934 Patent, has indirectly infringed by actively inducing its customers and agents to directly infringe the '934 Patent.

24. Qualyst has been and continues to be damaged by HμREL's infringement of the '934 Patent, in an amount to be determined at trial.

25. Qualyst has suffered irreparable injury for which there is no adequate remedy at law and will continue to suffer such irreparable injury unless HμREL's infringement of the '934 Patent is permanently enjoined by this Court.

26. HμREL was notified of the '934 Patent at least as early as March 19, 2015.
27. HμREL continued to infringe the '934 Patent after being notified.
28. HμREL's infringement is, and has been, willful.
29. HμREL's infringement of the '934 Patent is exceptional, and Qualyst is entitled to recover its reasonable attorneys' fees and costs incurred in prosecuting this action pursuant to 35 U.S.C. § 285.

RELIEF REQUESTED

WHEREFORE, Qualyst respectfully requests that the Court enter the following judgment and relief against HμREL:

- A. That HμREL has infringed the Patent-in-Suit;
- B. That HμREL, its officers, agents, and employees, and those persons in active concert or participation with any of them, and their successors and assigns be preliminarily and permanently enjoined from infringement of the Patent-in-Suit, including but not limited to an injunction against making, using, offering to sell, and selling within the United States, and importing into the United States, any products or performing methods covered by the Patent-in-Suit;
- C. That Qualyst be awarded all damages adequate to compensate it for HμREL's infringement of the Patent-in-Suit, such damages to be determined by a jury, and if necessary to adequately compensate Qualyst for the infringement, an accounting and treble damages as a result of HμREL's willful infringement;

D. That Qualyst be awarded pre-judgment and post-judgment interest at the maximum rate allowed by law;

E. That this case be declared an exceptional case within the meaning of 35 U.S.C. § 285 and that Qualyst be awarded its reasonable attorneys' fees, expenses, and costs incurred in connection with this action; and

F. That Qualyst be awarded such other and further relief as this Court deems just and proper.

SILLS CUMMIS & GROSS P.C.
Attorneys for Plaintiff
Qualyst Transporter Solutions, LLC

By: /s/Mark E. Duckstein
MARK E. DUCKSTEIN

Dated: June 5, 2015

JURY DEMAND

Qualyst hereby demands a trial by jury on all issues so triable.

SILLS CUMMIS & GROSS P.C.
Attorneys for Plaintiff
Qualyst Transporter Solutions, LLC

By: /s/Mark E. Duckstein
MARK E. DUCKSTEIN

Dated: June 5, 2015